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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,874	01/17/2006	Hiroyuki Shimoji	SAEG124.005APC	3870

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EXAMINER
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ORKIN, ALEXANDER J

ART UNIT	PAPER NUMBER
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4138

NOTIFICATION DATE	DELIVERY MODE
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09/18/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
eOAPilot@kmob.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/564,874	<b>Applicant(s)</b> SHIMOJI ET AL.	
	<b>Examiner</b> ALEXANDER ORKIN	<b>Art Unit</b> 4138	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/07/2006, 11/30/2007, 01/09/2008</u> .                      | 6) <input type="checkbox"/> Other: _____                          |



## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed April 7, 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document. A copy of Foreign Patent JP 3040930 was not supplied. Therefore it was not considered. However, all other documents were considered.

### ***Specification***

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The abstract of the disclosure is objected to because it may not exceed 150 words. Also it cannot use legal phraseology such as "wherein". Correction is required. See MPEP § 608.01(b).

***Claim Objections***

4. Claim 1 is objected to because of the following informalities: If there is only one thread, there cannot be two sewing ends based on its definition in the description of the reference numerals and in Figure 8. If there was one thread per chain, stitch then there could be multiple sewing ends. Also, it is not clear how the tubular shape is formed with just a single thread chain stitch and one or two sheet-like materials. If there are two sheet-like materials, then there must be more than one thread. Appropriate correction is required.
5. Claim 6 is objected to because of the following informalities: Two different thread ends cannot form a ring shape. Instead it would be in the shape of a semi circle (Fig. 12). Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
7. **Claims 1- 4, 10-14** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,063,097 to *Oi et al.* in view of U.S. Patent No. 6,984,242 to *Campbell et al.*

As to **claim 1**, *Oi* discloses a tubular suture reinforcement material made from a sheet-like material and a single thread. *Oi's* invention is described by combining

two sheets of materials by sewing two opposite sides to create the tubular structure. The ends of the threads are extended to a suitable length (Fig 1, col. 2, ll. 27-9). However, *Oi* lacks the chain stitch used in creating the tubular structure. Instead they disclose a normal stitch of a sewing yarn that is preferably bioabsorbable and biodegradable.

*Campbell* teaches the chain stitch concept using only one thread. The stitch has each loop going through the prior loop just like how the chain stitch is defined in this application (Fig. 3a and 3b, col. 6, ll. 49-53). *Campbell* explains that this type of stitch will create a removable seam. This removable seam will make it easy to separate the layers when the time is needed. This same function can be used in the stitch in *Oi*. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stitch of *Oi* with the chain stitch of *Campbell* in or order to create a tubular shape suture reinforcement material for an automatic suturing device.

As to **claim 2**, *Oi* also discloses the tubular reinforcement material having the tip part sewed in a tapering fashion (Fig. 7).

As to **claim 3**, *Oi* further discloses the material of the tubular suture reinforcement material being made up from a biodegradable and bioabsorbable knitted, woven, unwoven fabric etc (col. 2, ll. 45-7).

As to **claim 4**, *Oi* discloses that these materials can be stacked on top of each other with one of them being stretchable in order to make the tubular shape (col. 2, ll. 61-2).

As to **claim 10**, *Oi* disclose the method for manufacturing a tubular suture reinforcement material for an automatic suturing device by first sewing the sides of the sheet-like material to form the tubular structure. Second, extend the thread ends (col. 4, ll. 4-12).

As to **claim 11**, *Oi* further discloses the automatic suture device comprising a cartridge with staples and a frame that has a staple receiving slot wherein a tubular suture reinforcement material for an automatic suturing device is fitted to the cartridge and/or frame (Fig. 2).

As to **claim 12**, *Oi* discloses the method of removing an affected part of a tissue, which could be a lesion from a patient by first sandwiching the tissue in the unwoven fabrics. The tissue is then separated by a cutter. Finally the end of the suture is pulled to separate the section remaining in vivo and the section removed. This leaves part of the material inside the body, while removing some of the material along with the affected part (col. 4, ll. 23-31).

As to **claims 13 and 14**, *Oi* discloses using this method in either a soft tissue or in a pulmonary tissue (col. 1, ll.19-23, col. 4, ll. 23-4).

8. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,063,097 to *Oi et al.* in view of *Campbell* and further in view of U.S. Patent No. 6,273,897 to *Dalessandro et al.*

As to **claim 5**, *Oi* and *Campbell* teach the tubular suture reinforcement material. However, they lack the projections on the sewing portion of the reinforcement material.

*Dalessandro* teaches projections on a buttress or a suture reinforcement material. These projections can make it easier to slide the buttress onto the instrument (Fig 12, 13a, 13b, col. 3, ll. 50-2). This same function of using the projections to make it easier to slide a device on the instrument can be used with *Oi and Campbell* in loading the suture reinforcement material onto the instrument. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify tubular structure of *Oi* with the projection of *Dalessandro* in order to make it easier to load the tubular suture reinforcement material onto the automatic suturing device.



9. **Claims 6, 8, 9** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,063,097 to *Oi et al.* in view of *Campbell* and further in view of U.S. Patent No. 4,839,215 to *Starling et al.*

As to **claim 6, 8, 9** *Oi* and *Campbell* disclose the tubular suture reinforcement material. However, they lack the ring shape of the sewing ends, and other options of preventing the sutures of unraveling.

*Starling* teaches the ring shape of the sewing ends (Fig. 4). The ends of the two threads form the same ring like the shape as disclosed in this application in Figure 12. *Starling* teaches that by creating these rings, there will not be any stray suture ends that can cause problems or even untimely unravel. *Starling* also teaches other ways to prevent the suture from unraveling. *Starling's* configurations of the end of the suture comprise having the ends of the suture material drawn together and surrounded by several turns of another strand of the suture material (col. 14, ll. 4-8). These turns that *Starling* discloses can be in the form of different configurations of the ends of the suture that are found in claims 8 and 9 of this application. These turns will ultimately create the function of preventing the suture from an untimely unravel. Therefore this same function of creating rings at the end of the sutures, or adding a several turns in the ends of the suture in order to prevent unraveling and other errors involving bare suture ends can be used with *Oi and Campbell*. Therefore, It would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify

tubular structure of *Oi* and *Campbell* with sewing ends of *Sterling* to continue the thread so there are less free thread ends and to create the configuration from different turns so the threads do not unravel.

10. **Claims 7** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,063,097 to *Oi et al.* in view of *Campbell* and further in view of U.S. Patent No. 6,652,561 to *Tran*.

As to **claim 7**, *Oi* and *Campbell* disclose the tubular suture reinforcement material (Fig. 1). However, they lack the stopper going through the loops of the ends of threads that will prevent the suture from unraveling.

*Tram* teaches the stopper (Fig. 5g - 5i, col. 10. ll. 13-21). Tabs are said to twist around the loose ends of the suture. It is later said that the suture is tied in a knot with the anchor going through this knot. In these cases there is an external stopper, the external tabs, that is within the final loop of the suture that will prevent the suture from unraveling. The ultimate function is to have something intertwined in the final end or loop of the suture in order to prevent unravel. This same function of having a foreign object or stopper but in the final loop of the suture to prevent unraveling can be used with *Oi* and *Campbell* in order to prevent unraveling. Therefore, it would have been obvious to one of ordinary skill in the art to use the same type of stopper of *Tram* in *Oi* in order to prevent the suture from unraveling.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEXANDER ORKIN whose telephone number is (571)270-7412. The examiner can normally be reached on Monday-Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Melba Bumgarner can be reached on (571)272-4709. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 4138